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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/622,313	07/17/2003	Julian Alexander Barden	080404-000000US	4347

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EXAMINER

LOCKARD, JON MCCLELLAND

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 06/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/622,313	BARDEN ET AL.	
	Examiner	Art Unit	
	Jon M. Lockard	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 July 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-71 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-71 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION*Claim Objections*

1. Claim 17 objected to because of the following informalities: (1) it appears that claim 17 is two separate claims. The first part of claim 17 recites a probe of claim 7, wherein [t]he antibody is used in combination with a second antibody capable of detecting total P2X₇ expression; whereas the second part of claim 17 recites a probe that specifically binds an epitope outside residues Gly200 to Cys216 of a P2X₇ receptor; (2) it is unclear if the recitation of “a probe of claim 7, wherein [t]he antibody is used in combination with a second antibody capable of detecting total P2X₇ expression” is intended to be interpreted as a method claim or a product claim. It is noted that for the purposes of restriction, the claim has been interpreted to read on a probe that specifically binds an epitope outside residues Gly200 to Cys216 of a P2X₇ receptor. Appropriate correction is suggested.

2. Claim 27 is objected to because of the following informalities: it recites “probe as claimed claims 1”. Amendment of the claim to recite “... probe of claim 1”, or the like, would be remedial. Appropriate correction is suggested.

3. Claim 42 recites the limitation "wherein the disease or condition..." in line 1 of the claim. There is insufficient antecedent basis for this limitation in the claim. Claim 32, from which claim 42 depends, does not recite a disease or condition. Appropriate correction is suggested.

Election/Restrictions

4. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-6, 9-11, 14-15, 60, and 63, in so far as they are drawn to probes of undisclosed constitution adapted to distinguish between functional P2X₇ receptors and non-functional P2X₇ receptors, and compositions and kits comprising the same, classification dependent upon compound structure.
 - II. Claims 1-9, 11-15, 17, 32-40, 42-43, 50, 55-59, and 60-64, in so far as they are drawn to antibodies adapted to distinguish between functional P2X₇ receptors and non-functional P2X₇ receptors, wherein the antibodies bind an epitope extending from Gly200 to Cys216 of the P2X₇ receptor, and compositions and kits comprising the same, classified in class 530, subclass 387.9, for example.
 - III. Claims 16 and 71, drawn to antibodies which bind an epitope common to both functional and non-functional conformations of the P2X₇ receptor, and compositions and kits comprising the same, classified in class 530, subclass 387.9, for example.
 - IV. Claims 1-8, 14-15, 17, 32-37, 42-43, 50, 55-59, and 60-64, in so far as they are drawn to antibodies adapted to distinguish between functional P2X₇ receptors and non-functional P2X₇ receptors, wherein the antibodies bind an epitope outside residues Gly200 to Cys216 of the P2X₇ receptor, and compositions and kits comprising the same, classified in class 530, subclass 387.9, for example.
 - V. Claims 18-26 and 28-29, in so far as they are drawn to methods of detecting/diagnosing a disease/condition using a probe of undisclosed constitution

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which is adapted to distinguish between functional P2X₇ receptors and non-functional P2X₇ receptors, classification dependent upon compound structure.

- VI. Claim 27, drawn to an isolated cell or tissue sample complexed with a probe undisclosed constitution, classification dependent upon compound structure.
- VII. Claims 18-26 and 28-30, in so far as they are drawn to a method for detecting/diagnosing a disease/condition using an antibody which is adapted to distinguish between functional P2X₇ receptors and non-functional P2X₇ receptors, classified in class 435, subclass 7.1, for example.
- VIII. Claim 31, drawn to a method for treating irritable bowel syndrome comprising administering a compound of undisclosed constitution adapted to restore P2X₇ receptor function, classification dependent upon compound structure.
- IX. Claims 1-8, 10, 14-15, 32-37, 41-43, 50, and 55-63, in so far as they are drawn to an antibody which is adapted to distinguish between functional receptors having a sequence in which proline at amino acid 199 is in the trans conformation and non-functional receptors having a sequence in which the praline at amino acid 199 is in the cis conformation, and compositions and kits comprising the same, classified in class 530, subclass 387.9, for example.
- X. Claims 44-50, in so far as they are drawn to polypeptides comprising a segment of the P2X₇ receptor, and compositions and kits comprising the same, classified in class 530, subclass 324, for example.

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- XI. Claims 51, 53, 65, and 66, drawn to a composition comprising a compound of undisclosed constitution that regulates the expression of ATPases or ATPDases, classification dependent upon compound structure.
 - XII. Claims 52, 54, and 70, drawn to a method of treatment comprising administering a composition comprising a compound of undisclosed constitution that regulates the expression of ATPases or ATPDases, classification dependent upon compound structure.
 - XIII. Claims 67 and 69, in so far as they are drawn to methods of treatment or prevention comprising administering an antibody, classified in class 424, subclass 130.1, for example.
 - XIV. Claims 68 and 69, in so far as they are drawn to a method of treatment or prevention comprising administering a polypeptide, classified in class 514, subclass 12.
5. The inventions are distinct, each from the other because of the following reasons:
6. Inventions I, II, III, IV, VI, IX, X, and XI are independent and distinct, each from each other, because they are products which possess characteristic differences in structure and function and each has an independent utility that is distinct for each invention which cannot be exchanged.
7. The polypeptides of **Group X** and the antibodies of **Groups II, III, IV, and IX** are patentably distinct for the following reasons: while the inventions of both **Groups X and II, III, IV, and IX** are polypeptides, in this instance, the polypeptide of **Group X** is a single chain

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molecule, whereas the polypeptide of **Groups II, III, IV, and IX** encompass antibodies including IgG which comprises 2 heavy and 2 light chains containing constant and variable regions, including framework regions which act as a scaffold for the 6 complementary determining regions (CDRs) that function to bind an epitope. Thus, the polypeptide of **Group X** and the antibodies of **Groups II, III, IV, and IX** are structurally distinct molecules; any relationship between a polypeptide of **Group X** and an antibody of **Group II, III, IV, or IX** is dependent upon the correlation between the scope of the polypeptides that the antibody binds and the scope of the antibodies that would be generated upon immunization with a polypeptide.

8. Furthermore, searching the inventions of **Group X** and **Groups II, III, IV, and IX** would impose a serious search burden. The inventions have a separate status in the art as shown by their different classifications. A polypeptide and antibody which binds to the polypeptide require different searches. An amino acid search of the full-length protein is necessary for a determination of novelty and unobviousness of the protein. However, such a search is not required to identify the antibodies of **Group II, III, IV, or IX**. Furthermore, antibodies which bind to an epitope of a polypeptide of **Group X** may be known even if a polypeptide of **Group X** is novel. In addition, the technical literature search for the polypeptide of **Group X** and the antibody of **Group II, III, IV, or IX** is not coextensive, e.g. antibodies may be characterized in the technical literature prior to discovery of, or sequencing of, their binding target.

9. Inventions II, III, IV, and IX are directed to related products. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not

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capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, although classifications for the individual antibodies are overlapping, for instance 530/387.9, each represents a patentably distinct product, having different structures and binding to different amino acid sequences, and each would require separate sequence searches. Furthermore, searching the 4 different inventions would impose a serious search burden since a search of the antibody of Group II, for example, would not be used to determine the patentability of any of the other 3 antibodies, and vice-versa.

10. Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

11. Each of inventions I, (II, III, IV, and IX), VI, X, and XI are unrelated to each other. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the probes of undisclosed constitution that distinguish between functional and non-functional P2X₇ receptors, the antibodies that distinguish between functional and non-functional P2X₇ receptors, the cell/tissues that are complexed with a probe of undisclosed constitution, the polypeptide fragments, and the compounds of undisclosed constitution that regulate expression of ATPases and ATPDases are all physically and functionally distinct chemical entities that have different structures, activities, and functions. Furthermore, searching the inventions of Groups I, II, III, IV, VI, IX, X, and XI would impose a serious search burden since a search of the antibody of Group II, for example, would not be used

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to determine the patentability of the compounds of that regulate expression of ATPases and ATPDases of Group XI, for example, and vice-versa.

12. Invention I and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product, or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the method of disease detection of Invention V can be practiced with an antibody of Invention II, for example, which is a materially different product.

13. Invention I and each of VII, VIII, XII, XIII, and XIV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04 and 808.01). In the instant case the different Inventions of I and each of VII, VIII, XII, XIII, and XIV are unrelated product and methods, wherein each is not required, one for another. For example, the claimed Inventions VII, VIII, XII, XIII, and XIV do not require the use of the probe of undisclosed constitution of Invention I.

14. Invention II and each of VII and XIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product, or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody of Invention II can be used to

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detect the presence of the polypeptide, but the antibody can also be used in a method of modulating polypeptide activity, in a method of treatment, or in a method of purifying the polypeptide, which are all materially different methods.

15. Invention II and each of V, VIII, XII, and XIV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04 and 808.01). In the instant case the different Inventions of II and each of V, VIII, XII, and XIV are unrelated product and methods, wherein each is not required, one for another. For example, the claimed Inventions V, VIII, XII, and XIV do not require the use of the antibody of Invention II.

16. Invention III and each of VII and XIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product, or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody of Invention III can be used to detect the presence of the polypeptide, but the antibody can also be used in a method of modulating polypeptide activity, in a method of treatment, or in a method of purifying the polypeptide, which are all materially different methods.

17. Invention III and each of V, VIII, XII, and XIV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04 and 808.01). In the instant case the different Inventions of III and each of V, VIII, XII, and XIV are unrelated

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product and methods, wherein each is not required, one for another. For example, the claimed Inventions V, VIII, XII, and XIV do not require the use of the antibody of Invention III.

18. Invention IV and each of VII and XIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product, or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody of Invention IV can be used to detect the presence of the polypeptide, but the antibody can also be used in a method of modulating polypeptide activity, in a method of treatment, or in a method of purifying the polypeptide, which are all materially different methods.

19. Invention IV and each of V, VIII, XII, and XIV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04 and 808.01). In the instant case the different Inventions of IV and each of V, VIII, XII, and XIV are unrelated product and methods, wherein each is not required, one for another. For example, the claimed Inventions V, VIII, XII, and XIV do not require the use of the antibody of Invention IV.

20. Invention VI and each of V, VII, VIII, XII, XIII, and XIV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04 and 808.01). In the instant case the different Inventions of VI and each of V, VII, VIII, XII, XIII,

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and XIV are unrelated product and methods, wherein each is not required, one for another. For example, the claimed Inventions V, VII, VIII, XII, XIII, and XIV do not require the use of the cells/tissues complexed with a probe of Invention VI.

21. Invention IX and each of VII and XIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product, or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody of Invention IX can be used to detect the presence of the polypeptide, but the antibody can also be used in a method of modulating polypeptide activity, in a method of treatment, or in a method of purifying the polypeptide, which are all materially different methods.

22. Invention IX and each of V, VIII, XII, and XIV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04 and 808.01). In the instant case the different Inventions of IX and each of V, VIII, XII, and XIV are unrelated product and methods, wherein each is not required, one for another. For example, the claimed Inventions V, VIII, XII, and XIV do not require the use of the antibody of Invention IX.

23. Invention X and Invention XIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product, or (2) the

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product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide fragments Invention X can be used in the treatment method of Invention XIV, but the polypeptide fragments can also be used in a method of generating antibodies or in an *in vitro* assay, which are all materially different methods.

24. Invention X and each of V, VII, VIII, XII, and XIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04 and 808.01). In the instant case the different Inventions of X and each of V, VII, VIII, XII, and XIII are unrelated product and methods, wherein each is not required, one for another. For example, the claimed Inventions V, VII, VIII, XII, and XIII do not require the use of the polypeptide fragments of Invention X.

25. Invention XI and Invention XII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product, or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the method of treatment of Invention XII can be practiced with an antibody, which is a materially different product.

26. Invention XI and each of V, VII, VIII, XII, and XIV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04 and 808.01). In the instant case the different Inventions of XI and each of V, VII, VIII, XII, and XIV

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are unrelated product and methods, wherein each is not required, one for another. For example, the claimed Inventions V, VII, VIII, XII, and XIV do not require the use of the compound that regulates expression of ATPases and ATPDases of Invention XI.

27. Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive Inventions that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: Inventions V, VII, VIII, XII, XIII, and XIV are directed to methods that are distinct both physically and functionally, have different method steps, starting compounds, and goals, and are not required one for the other.

28. Invention V requires search and consideration of detecting a disease using a probe of undisclosed constitution, which is not required by any of the other Inventions. Invention VII requires search and consideration of detecting irritable bowel syndrome using an antibody, which is not required by any of the other Inventions. Invention VIII requires search and consideration of treating irritable bowel syndrome by administering a compound that restores function of the P2X₇ receptor, which is not required by any of the other inventions. Invention XII requires search and consideration of treatment with a composition that regulates expression of ATPases or ATPDases, which is not required by any of the other inventions. Invention XIII requires search and consideration of treatment by administering an antibody, which is not required by any of the other Inventions. Invention XIV requires search and consideration of treatment by administering a polypeptide, which is not required by any of the other Inventions. Therefore, each method is divergent in materials and steps. For these reasons, Inventions V, VII, VIII, XII,

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XIII, and XIV are patentably distinct. Furthermore, the distinct steps and products require separate and distinct, non-coextensive searches. The inventions of Groups V, VII, VIII, XII, XIII, and XIV have a separate status in the art as shown by their separate search requirements. As such, it would be burdensome to search the inventions of Groups V, VII, VIII, XII, XIII, and XIV together.

29. Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, and the search required for each group is not required for the other groups because each group requires a different non-patent literature search due to each group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

Election of Species:

30. Claims 1-13, 18-26, 32-41, 50-52, 55-59, and 65-70 are generic to the following disclosed patentably distinct species of disease/condition:

- (1) prostate cancer
- (2) breast cancer
- (3) skin cancer
- (4) lung cancer
- (5) cervix cancer
- (6) uterus cancer
- (7) stomach cancer
- (8) oesophagus cancer
- (9) bladder cancer
- (10) colon cancer
- (11) vaginal cancer
- (12) epithelial cell cancers
- (13) malignant lymphoma
- (14) blood cancers

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- (15) irritable bowel syndrome
- (16) viral infection
- (17) bacterial infection

31. The species are independent or distinct because they have different etiologies, symptoms, and physiological results, and would require separate search and consideration. Furthermore, search of more than one disorder or condition would constitute a burden on the Office. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

32. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

33. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

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34. The Examiner has required restriction between product and method claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn method claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Method claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

35. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined method claims will be withdrawn, and the rejoined method claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and method claims may be maintained. Withdrawn method claims that are not commensurate in scope with an allowed product claim will not be rejoined. See “Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b),” 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the method claims should be amended during prosecution either to maintain dependency on the method claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

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36. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the Examiner before the patent issues. See MPEP § 804.01.

37. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

38. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jon M. Lockard, Ph.D.** whose telephone number is **(571) 272-2717**. The examiner can normally be reached on Monday through Friday, 8:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Brenda Brumback**, can be reached on **(571) 272-0961**.

The fax number for the organization where this application or proceeding is assigned is **571-273-8300**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

Jon M. Lockard, Ph.D.
June 14, 2006

**CHRISTINE J. SAOUD
PRIMARY EXAMINER**

Christine J. Saoud